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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,213	02/12/2002	Hak-Kim Chan	A-60010-1/RFT/DLR	9021

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EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,213	CHAN ET AL.	
	Examiner	Art Unit	
	Jon P Weber, Ph.D.	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20020807</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Objections/Status of the Claims

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 9-25 filed in the amendment of 08 May 2002 have been renumbered 17-33. The originally filed claims were 1-16. Claims 2-16 were canceled with the preliminary amendment of 12 February 2002, leaving only claim 1. The amendment of 08 May 2002 to cancel claims 1-8 and add claims 9-25 has been interpreted to cancel claim 1 and add claims 17-33, as renumbered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 26 recite “DNase” but fail to identify which DNase is intended. There are several types of DNase and from many different organisms. The metes and bounds of the claims are unclear.

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Claims 17-18 are confusing because it is not clear if the temperature step is required to minimize the aggregation or the aggregation is minimized in spite of the identified elevated temperature.

Claims 19-22 and 28-30 are vague and indefinite because it is not clear if the DNase-containing solutions have the recited pH values, or these pH values are intended use. That is, are these actual limiting properties or not? The claims recite “reducing the pH” but fail to indicate the starting pH value from which the solution is reduced, and therefore lack clear antecedent basis. Further, is the pH reducing step before, after, or simultaneous with changes in the temperature?

Claim 32 is not a proper Markush group.

Claim 33 recites “further comprises the steps of spray-drying” which lacks clear antecedent basis because the process is directed to a method of making a solution not a solid.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19, 22-24, 26-28 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Heicke et al. (1969).

Heicke et al. (1969) disclose purifying DNase from *Verongia aerophoba* on a 5-20% linear sucrose density gradient at pH 5.0 (see Fig. 1, for example). The DNase peak is collected

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in factions at ~14% sucrose (range of ~11-16%), 140 mg/ml, or ~0.41 M sucrose (FW=342.301).

This is an inherency rejection for the method. At page 165, column 2, Heicke et al. state that DNase is unstable in alkaline solution, even at pH 7-8, which was why they kept the pH at 5.0.

Claims 17-19, 22, 24, 26-28 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Khouw et al. (US 4,065,355).

Khouw et al. (US 4,065,355) disclose eluting DNase from ConA-sepharose with carbohydrate solutions containing various 2% (20 mg/ml) solutions of sugars including sucrose and mannitol (Table III).

Claims 17-18, 23-24, 26-27 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Karimov et al. (1982).

Karimov et al. (1982) disclose 0.4 M mannitol and DNase in solution to liberate DNA from chloroplasts. The pH is not indicated in the abstract.

These compositions are the same as instantly claimed and must inherently have the same properties even if not so recognized in the prior art reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Heicke et al. (1969) in view of Arakawa et al. (1982), Back et al. (1979) and van de Beek et al. (1969).

The teachings of Heicke et al. (1969) have been discussed above. Heicke et al. (1969) lack solution pH values of 6 and 6.5 and do not spray dry the solution.

Arakawa et al. (1982) disclose that polyhydric alcohols and sugars stabilize the structure of proteins in general. Several enzymes are exemplified.

Back et al. (1979) disclose that polyhydric alcohols and sugars stabilize the structure of proteins in general. Several proteins and enzymes are exemplified.

van de Beek et al. (1969) disclose that sugars and polyhydric alcohols are known in the art to preserve the activity of enzymes against irreversible denaturation, and specifically disclose stabilizing rennin during spray-drying and storage.

A person of ordinary skill in the art at the time the invention was made would have been motivated to use pH values between 7.0 and 5.0 in the DNase/sucrose solutions of Heicke et al. (1969) because Heicke et al. (1969) clearly indicate that pH values of DNase below 7.0 are more stable. Similarly a person of ordinary skill in the art at the time the invention was made would have been motivated to add sugars or polyhydric alcohols to stabilize DNase because Arakawa et al. (1982), Back et al. (1979) and van de Beek et al. (1969) establish that stabilization of proteins by sugars and polyhydric alcohols is a general phenomenon and well-adapted to use in spray drying.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to stabilize DNase with sugars and/or pH values less than 7.0.

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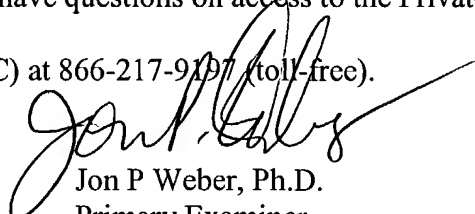
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925.

The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
2 April 2004